K082071

AdPharma
Advanced Solutions to Pharma Safety & Success

OCT 02 2008

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5. 510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter.....	AdPharma, Inc. 415 West Golf Road #57 Arlington Heights, IL 60005
Contact Person.....	Dr. Vivek Ramana, MD Executive Vice-President of Clinical Affairs and Chief Operating Officer Phone: (847) 806-6789 Cell phone: (203) 314-1417 Fax: (847) 806-6791 email: vramana@ad-pharma.com
Date Summary was Prepared.....	6/16/08
Trade Name:.....	AdPharma™ Occlude® Dentin Tubule Agent AdPharma™ Occlude® F Dentin Tubule Agent
Common Name(s):.....	Dentin Desensitizer; Dentin Sealer; Cavity Varnish; Dentin Tubule Protection
Recommended Classification:.....	Cavity Varnish (21CFR 872.3260, Product Code LBH, Class II Dental Device)
Predicate Device:.....	Centrix D/SENSE II Dentin Desensitizer 510(k) # K992629

Description of the Device:
AdPharma™ Occlude® Dentin Tubule Agents are for use in one of a number of steps normally involved in the restoration of teeth. This device comes into use following the dentin-etching step and prior to the application of a dentin adhesive or adhesive/primer. The Occlude® is applied to the exposed dentin and the solvent evaporated off, leaving the active glass. It is also

anticipated to market Occlude® Dentin Tubule Agents combined with a commercially available, non-aqueous dentin adhesive to condense these two application steps into one step. In vitro testing indicated this combination version is still efficacious. The Occlude® is manufactured in such a way that it is intended to enter the exposed dentin tubules and penetrate to a greater depth than the adhesive itself or adhesive/primer itself.

Indications for use:
Desensitizing agents for dentin surfaces by occluding dentin tubules to help prevent micro-leakage. Use Occlude® under direct or indirect restorations following dentin etch and prior to dentin adhesive application. Use Occlude® as a desensitizing agent for use in treatment of cervical erosion in Class V restorations.

Substantial Equivalence:
The information included in this 510(k) Pre-market Notification shows that the AdPharma™ Occlude® Dentin Tubule Agents are substantially equivalent to the predicate device in terms of indications for use and safety characteristics. A biocompatibility assessment was completed for the Occlude® Dentin Tubule Agents indicating them to be safe for use in body.

Bench testing includes micro-leakage and bond strength determinations. This micro-leakage testing demonstrates Occlude® Dentin Tubule Agents work for their intended use of reducing micro-leakage, thus reducing sensitivity. The bond strength determinations demonstrate that Occlude® Dentin Tubule Agents do not exhibit adverse affects on bond strengths.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

Dr. Vivek Ramana
Executive Vice-President of Clinical Affairs
AdPharma, Incorporated
415 West Golf Road #57
Arlington Heights, Illinois 60005

Re: K082071
Trade/Device Name: AdPharma™ Occlude® Dentin Tubule Agent
AdPharma™ Occlude® F Dentin Tubule Agent
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: July 11, 2008
Received: July 22, 2008

Dear Dr. Ramana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K082071 MCM

Device Name: AdPharma™ Occlude® Dentin Tubule Agent /

AdPharma™ Occlude® F Dentin Tubule Agent

Indications for Use:

Desensitizing agent for dentin surfaces by occluding dentin tubules to help prevent micro-leakage. Use under direct or indirect restorations following dentin etch and prior to dentin adhesive application. Desensitizing agent for use in treatment of cervical erosion in Class V restorations.

Prescription Use ___X_____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082071